participation and accompanying information, FDA will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Each presentation will be limited in time in order to provide sufficient time for prepared presentations by the agency followed by a discussion period. The schedule of the public meeting will be available at the meeting, and later it will be placed on file in the Dockets Management Branch (address above).

Individuals and organizations that do not submit a notice of participation but would like to testify will have the opportunity, if time permits. A transcript of the proceedings of the public meeting, as well as all data and information submitted voluntarily to FDA during the public meeting to discuss the working draft, will become part of the administrative record and will be available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above).

While oral presentations from specific individuals and organizations will be limited during the public meeting, the written comments submitted as part of the administrative record may contain a discussion of any issues of concern. All relevant data and documentation should be submitted with the written comments.

There will also be a public meeting with the Device GMP Advisory Committee, established under section 520(f)(1)(B) of the act, on the working draft. That meeting will be governed by part 14 (21 CFR part 14) of FDA's administrative practices and procedures regulations, which specifies the requirements for filing notices of appearance. The tentative dates for the meeting are September 13 and 14, 1995. A notice of the exact dates, time, and place for the meeting will appear in a future issue of the **Federal Register**. After considering the written comments and the views expressed at the public meeting and at the September advisory committee meeting, FDA will publish a final rule in the **Federal Register**.

IV. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

(1) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.''

(2) ISO working draft revision of ISO/DIS 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001.''

V. Comments

Interested persons may, on or before October 23, 1995, submit to the Dockets Management Branch (address above), written comments regarding this working draft. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The working draft and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–18080 Filed 7–19–95; 1:36 pm]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL–5260–2]

Approval of Existing Federally Enforceable State and Local Operating Permit Programs To Limit Potential To Emit for Air Toxics; State of Alabama; Knox County, Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes approval of the State of Alabama's Federally enforceable state operating permits program (FESOP) under section 112(l) of the Clean Air Act as amended in 1990 (CAA). EPA proposes approval of the Knox County, Tennessee Federally enforceable local operating permit program (FELOP) under section 112(l) of the CAA. EPA is proposing approval of both of these requests under section 112(l) of the CAA for purposes of limiting potential to emit (PTE) for hazardous air pollutant (HAP) sources. In the final rules section of this **Federal Register**, EPA is approving Alabama and Knox County, Tennessee's submittals as a direct final rule without prior proposal because the EPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by August 23, 1995.

ADDRESSES: Written comments should be addressed to Scott Miller of the EPA Regional office listed below.

Copies of the material submitted by both agencies may be examined during normal business hours at the following locations:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street NE., Atlanta, Georgia 30365.

Alabama Department of Environmental Management, Air Division, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109.

Knox County Department of Air Pollution Control, City/County Building, Suite 339, 400 West Main Street, Knoxville, Tennessee 37902.

FURTHER INFORMATION CONTACT: Scott Miller, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365. The telephone number is 404/347–2864.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: June 23, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95–17614 Filed 7–21–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 95

RIN 0970–AB46

Reduction of Reporting Requirements for the State Systems Advance Planning Document (APD) Process

AGENCY: Administration for Children and Families, HHS.